

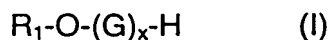
**WHAT IS CLAIMED IS:**

1. A composition comprising at least one antigenic medium and at least one adjuvant, wherein:
  - 5 (a) the at least one antigenic medium and the at least one adjuvant each comprise one or more phases which are distinct from each other when the composition is in a solid state, and
  - (b) the composition is in the liquid state when its temperature is greater than or equal to 4°C.
- 10 2. The composition as defined in Claim 1, wherein the various phases comprising the composition in the solid state are adjacent to at most two distinct phases.
3. The composition as defined in Claim 2, wherein the various phases comprising the composition in the solid state are arranged in a stratified manner in  
15 said composition.
4. The composition as defined in Claim 3, wherein the various phases comprising the composition in a solid state are superposed one on top of another.
5. The composition as defined in Claim 1, wherein the antigenic medium comprises a lyophilisate of antigenic material.
- 20 6. The composition as defined in Claims 1, wherein the antigenic medium is an aqueous or aqueous-alcoholic phase of antigenic material.
7. The composition as defined in Claim 1, comprising at least one aqueous or aqueous-alcoholic adjuvant phase comprising at least one water-soluble salt of a metal cation and of an organic acid possessing at least one phosphoric group or one  
25 carboxyl group.

8. The composition as defined in Claim 7, in which the at least one water-soluble salt of a metal cation is a salt of manganese, aluminum, calcium or zinc.
9. The composition as defined in Claim 7, in which the at least one water-soluble salt of a metal cation is a salt of glycerophosphoric, acetic, lactic, tartaric, malic,  
5 citric, pyruvic, gluconic, glucuronic, fructoheptonic, gluconoheptonic, glucoheptonic, glutamic, or aspartic acids or methionine.
10. The composition as defined in Claim 9, in which the at least one water-soluble salt of a metal cation is manganese gluconate, calcium gluconate, zinc gluconate, calcium fructoheptonate, calcium glycerophosphate, soluble aluminum acetate or  
10 aluminum salicylate.
11. The composition as defined in Claim 1, comprising at least one aqueous or aqueous-alcoholic adjuvant phase comprising a surfactant or a mixture of surfactants, having an overall HLB number of between 5 and 15.
12. The composition as defined in Claim 11, in which the surfactant or the mixture  
15 of surfactants is a modified fatty substance having an overall HLB number of between 6 and 14.
13. The composition as defined in Claim 12, in which the modified fatty substance is an ethoxylated derivatives of an oil having a number of EOs of between 1 and 60.
14. The composition as defined in Claim 13, comprising alkoxylated derivatives of  
20 maize oil, mixtures of alkoxylated derivatives of maize oil, having an overall HLB number of between 10 and 14, or ethoxylated derivatives of castor oil or mixtures of alkoxylated derivatives of castor oil, having an overall HLB number of between 7 and 10.
15. The composition as defined in Claim 1, comprising at least one aqueous or  
25 aqueous-alcoholic adjuvant phase comprising an alkoxylated derivative of an ester of

a fatty acid and of a polyol or an alkoxylated derivative of an ether of a fatty alcohol and of a polyol.

16. The composition as defined in Claim 15, in which the alkoxylated derivative of the ester of the fatty acid and of the polyol is a triglyceride of an alkoxylated fatty acid, the alkoxylated ester of polyglycerol and of a fatty acid, the alkoxylated ester of the fatty acid with a hexol or the alkoxylated ester of the fatty acid with a hexol anhydride.
17. The composition as defined in Claim 16, wherein the hexol is sorbitol or mannitol.
18. The composition as defined in Claim 16, wherein the hexol anhydride is sorbitan or mannitan.
19. The composition as defined in Claim 15, wherein the esters of fatty acids comprise acyl radicals comprising from 12 to 22 carbon atoms.
20. The composition as defined in Claim 19, wherein said acyl radicals comprise from 16 to 18 carbon atoms.
21. The composition as defined in Claim 19, in which the acyl radicals of said fatty acid esters are derived from oleic, ricinoleic or isostearic acids.
22. The composition as defined in Claim 15, comprising at least one aqueous or aqueous-alcoholic adjuvant phase comprising an ethoxylated derivative of mannitan oleate having a number of EOs of between 5 and 15.
23. The composition as defined in Claim 22, comprising an ethoxylated derivative of mannitan oleate having a number of EOs of between 7 and 11.
24. The composition as defined in Claim 1, comprising at least one aqueous or aqueous-alcoholic adjuvant phase comprising:
  - a) a compound of formula (I):



in which  $R_1$  represents a saturated or unsaturated, linear or branched hydrocarbon radical comprising from 1 to 30 carbon atoms, G represents the residue of a saccharide and x represents a decimal number of between 1 and 5 or a mixture of compounds of formula (I), and if desired

b) a compound of formula (II):



in which  $R_2$  represents, independently of  $R_1$ , a saturated or unsaturated, linear or branched hydrocarbon radical comprising from 8 to 30 carbon atoms or a mixture of compounds of formula (II).

25. The composition as defined in Claim 24, for which, in the formula (I), the number x, which represents an average degree of polymerization of the saccharide, is between 1 and 3.

26. The composition as defined in Claim 25, wherein the average degree of polymerization of the saccharide is between 1.05 and 2.5.

27. The composition as defined in Claim 26, wherein the average degree of polymerization of the saccharide is between 1.1 and 2.0.

28. The composition as defined in Claim 27, wherein the average degree of polymerization of the saccharide is less than or equal to 1.5.

29. The composition as defined in Claim 24, for which, in the formula (I), G represents more particularly a glucose residue or a xylose residue.

30. The composition as defined in Claim 24, for which, in the formula (I), the radical  $R_1$  represents a radical comprising from 5 to 22 carbon atoms chosen from pentyl, hexyl, heptyl, octyl, nonyl, decyl, undecyl, dodecyl, tridecyl, tetradecyl, pentadecyl, hexadecyl, heptadecyl, octadecyl, nonadecyl, eicosyl, uneicosyl,

docosyl, heptadecenyl, eicosenyl, uneicosenyl, docosenyl, heptadecadienyl or decenyl radicals, said radicals being linear or branched.

31. The composition as defined in Claim 30, for which, in the formula (I),  $R_1$  preferably represents a radical comprising from 8 to 20 carbon atoms, said radicals  
5 being linear or branched.

32. The composition as defined in Claim 24, for which, in the formula (II),  $R_2$  represents a radical comprising from 8 to 22 carbon atoms chosen from octyl, nonyl, decyl, undecyl, dodecyl, tridecyl, tetradecyl, pentadecyl, hexadecyl, heptadecyl, octadecyl, nonadecyl, eicosyl, uneicosyl, docosyl, heptadecenyl, eicosenyl,  
10 uneicosenyl, docosenyl, heptadecadienyl or decenyl radicals, said radicals being linear or branched.

33. The composition as defined in Claim 24, for which, when the adjuvant phase comprises at least one compound of formula (I) and at least one compound of formula (II), the compound of formula (I)/compound of formula (II) weight ratio is  
15 between 10/90 and 90/10.

34. The composition as defined in Claim 33, wherein the weight ration is between 10/90 and 60/40.

35. The composition as defined in Claim 1, comprising at least one oily adjuvant phase, it being understood that when the antigenic medium comprises a lyophilisate  
20 comprising one or more antigens, the composition also comprises either at least one aqueous or aqueous-alcoholic adjuvant phase comprising one or more water-soluble salts of metal cations and of organic acids possessing at least one phosphoric group or one carboxyl group, or a diluent phase for the antigenic medium.

36. The composition as defined in Claim 35, wherein the at least one oily adjuvant  
25 phase is a mineral oil, a synthetic oil, a vegetable oil or an animal oil.

37. The composition as defined in Claim 36, comprising in combination (i) the oil or the mixture of oils comprising the oily phase and (ii) a nonionic surfactant or a mixture of nonionic surfactants.
38. The composition as defined in Claim 37, wherein one of the nonionic  
5 surfactants combined with the oil or with the mixture of oil is oleic, ricinoleic or ketostearic acid or a derivative thereof.
39. The composition as defined in Claim 38, wherein one of the nonionic surfactants combined with the oil or with the mixture of oil is a mannitol oleate or a derivative of mannitol oleate obtained by grafting a hydrophilic functional group.
- 10 40. The composition as defined in Claim 39, wherein said hydrophilic group is an amide, amine, alcohol, polyol or a carboxyl functional group or ethoxy, propoxy and/or butoxy radical or a mannitan oleate or a derivative thereof.
41. The composition as defined in Claim 35, comprising a single oily adjuvant phase.
- 15 42. The composition as defined in Claim 41, wherein, in the solid state, the oily phase comprises the bottom phase of said composition.
43. The composition as defined in Claim 1, further comprising at least one diluent phase for at least one of the antigenic phases, whose diluent character is expressed when said composition is in the liquid state and which, when the composition is in  
20 the solid state, is distinct from the antigenic phase or from the antigenic phases and from the adjuvant phase or from the adjuvant phases.
44. The composition as defined in Claim 1, further comprising at least one diluent phase for at least one of the adjuvant phases, whose diluent character is expressed when said composition is in the liquid state and which, when the composition is in

the solid state, is distinct from the antigenic phase or from the antigenic phases and from the adjuvant phase or from the adjuvant phases.

45. The composition as defined in Claim 1, which does not comprise an oily phase.

5 46. The composition as defined in Claim 35, comprising an antigenic phase and an oily adjuvant phase.

47. The composition as defined in Claim 35, comprising an antigenic phase, an oily adjuvant phase and a diluent phase for the antigenic phase.

10 48. The composition as defined in Claim 46, wherein, in the solid state, the oily phase comprises a bottom layer and the antigenic phase a top phase.

49. A method for preparing a composition comprising at least one antigenic medium, at least one adjuvant, and optionally a diluent, wherein the at least one antigenic medium and the at least one adjuvant each comprise one or more phases which are distinct from each other when the composition is in a solid state, and the  
15 composition is in the liquid state when its temperature is greater than or equal to 4°C, said method comprising the steps of:

- a) bringing a first of an adjuvant, diluent or antigenic phases, which is liquid at room temperature, to a temperature of less than or equal to its solidification point so as to form a first solid phase,
- 20 b) adding a second of the other antigenic, adjuvant or diluent phases, in the liquid state, over the solid phase prepared in a), and then bringing the new combination to a temperature of less than or equal to the lowest solidification point of the two phases so as to form a solid combination with two distinct phases,

- c) adding, where appropriate, a new antigenic, adjuvant or diluent phase, in the liquid state, over said solid combination prepared in step b), and then bringing the new combination to a temperature of less than or equal to the lowest solidification point of the three phases so as to form a solid combination with three distinct phases, and
- d) repeating the sequence of operations carried out in step c), where appropriate, until the last of the antigenic, adjuvant or diluent phases comprising said composition has been frozen.

50. The method as defined in Claim 49, for preparing a composition comprising an antigenic phase, an oily adjuvant phase and optionally a diluent phase for the antigenic phase, in which the phase used in step a) is the oily adjuvant phase, the phase used in step b) is either the diluent phase, when the composition comprises one, or the antigenic phase, and the phase used, where appropriate, in step c) is the antigenic phase.

51. An immunogenic composition comprising the composition as defined in Claim 1 and a carrier suitable for parenteral or intravenous injection.

52. Method for freezing preservation of a composition comprising at least one antigenic medium, at least one adjuvant and optionally at least one diluent for said antigenic medium and/or for said adjuvant, comprising the steps of:

- a) bringing a first of the adjuvant, diluent or antigenic phases, which is liquid at room temperature, to a temperature of less than or equal to its solidification point so as to form a first solid phase,
- b) adding a second of the other antigenic, adjuvant or diluent phases, in the liquid state, over the solid phase prepared in a), and then bringing the new combination to a temperature of less than or equal to the



lowest solidification point of the two phases so as to form a solid combination with two distinct phases,

- c) adding, where appropriate, a new antigenic, adjuvant or diluent phase, in the liquid state, over said solid combination prepared in step b), and then bringing the new combination to a temperature of less than or equal to the lowest solidification point of the three phases so as to form a solid combination with three distinct phases,
- d) repeating the sequence of operations carried out in step c), where appropriate, until the last of the antigenic, adjuvant or diluent phases constituting the said composition has been frozen, and
- e) keeping the composition thus frozen at a temperature lower than the lowest freezing point of said phases constituting it.

53. The method as defined in Claim 52, for preserving a composition comprising an antigenic phase, an oily adjuvant phase and optionally a diluent phase for the antigenic phase, in which the phase used in step a) is the oily adjuvant phase, the phase used in step b) is either the diluent phase, when the composition comprises one, or the antigenic phase, and the phase used, where appropriate, in step c) is the antigenic phase.